To all user of the following systems ARTIS icono and ARTIS pheno (Software VE20B)

Product/Trade Name:	ARTIS icono biplane, ARTIS icono floor, ARTIS pheno
Material number:	11327600, 11327700, 10849000

E-mail	advancedtherapies-fsca.team@siemens-healthineers.com
Date	September, 2020
Corrective Action ID	AX061/20/S

Customer Safety Information (CSI) for Field Safety Corrective Action

Subject: Potential "DSA Roadmap" inaccuracy of your ARTIS icono and ARTIS pheno systems

Dear Customer,

We would like to inform you about a potential issue with the "DSA Roadmap" application of your ARTIS icono and ARTIS pheno systems and a corrective action that will be performed.

What is the issue and when does it occur?

In the "DSA Roadmap" application the ARTIS system's intended behavior is to move automatically to the reference position of the previously acquired DSA while driving with "Automap" function. In rare cases, when the DSA acquisition has been started while C-Arm or table is moving there might be a shift between the image acquired at start position and the image (i.e. DSA vessel map) taken at reference position.

What is the impact on the operation of the system and what are the possible risks?

This might lead to a DSA vessel map being overlaid to a subtracted fluoro image at a position that does not fulfill our requirements for accuracy. If the displacement relative to the vessel tree is very large, it might be recognized by the user. However, if the displacement is slight or at an unfavorable plane, the user might rely on incorrect visualization of the catheter relative to the vessel map. This might imply danger for the patient. A similar risk exists in case of patient movement between acquiring the DSA vessel map and using it as mask for later roadmap procedures.

Siemens Healthcare GmbH
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How was the issue identified and what is the root cause?

The problem was identified by regular field observation. The root cause of this problem is a rare synchronisation condition leading to this software error. It occurs only if the user starts initiating acquisition (e.g. by pressing the pedal of the footswitch) of the later used DSA scene while the system is still moving.

Which steps have to be taken by the user to avoid the possible risks associated with this issue?

We strongly recommend to not start releasing x-ray for DSA (e.g. by pressing the pedal of the footswitch) until the system reaches the target position and stopped moving!

What actions are being taken by the manufacturer to mitigate possible risks?

The software in the affected systems will be updated to correct the issue.

What is the efficiency of the corrective action?

The software update will prevent the system from entering above erroneous state.

How will the corrective action be implemented?

Our service organization will get in contact with you for an appointment to perform the corrective action. Please feel free to contact our service organization for an earlier appointment.

This letter will be distributed to affected customers as update AX062/20/S.

What risks are there for patients who have previously been examined or treated using this system?

We do not consider it necessary to re-examine any patients in this case.

This is a possible software defect that has no influence on previous diagnosis and treatment of patients in all cases where the outcome was deemed to be sufficient by the physician responsible.

Please ensure that all users of the affected products within your organization and others who may need to be informed will receive the safety relevant information provided with this notice and will comply with the recommendations therein.

We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is retained in your product related records appropriately. Please keep this information at least until the measures have been finalized.

Please forward this safety information to any other organizations that could be affected by this measure.

If the device has been sold and is therefore no longer in your possession, please forward this safety notice to the new owner. We would also request you to inform us of the identity of the device's new owner where possible.

With best regards,

Siemens Healthcare GmbH
Business Area Advanced Therapies (AT)

i. V. Reinmar Killmann

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